UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FERRING B.V., FERRING INTERNATIONAL CENTER S.A., and FERRING PHARMACEUTICALS INC.,

Plaintiffs and Counter-Defendants,

-against-

No. 17 Civ. 9922 (CM)

SERENITY PHARMACEUTICALS, LLC, REPRISE BIOPHARMACEUTICS, LLC, AVADEL SPECIALTY PHARMACEUTICALS, LLC,

Defendants and Counterclaimants.

DECISION AND ORDER GRANTING PLAINTIFFS' MOTION TO DISMISS AND DENYING AS MOOT DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

McMahon, C.J.:

While this case is a patent case at its core, the parties have opened a second front of battle over the trademarks to their competing pharmaceutical products. This decision eliminates that that second front.

On June 28, 2018, Serenity Pharmaceuticals, LLC ("Serenity"), Reprise Biopharmaceutics LLC ("Reprise"), Avadel Specialty Pharmaceuticals, LLC ("Avadel") (collectively, the "Counterclaimants") filed a counterclaim seeking a declaration that the mark for their pharmaceutical product, "Noctiva"—a nasal spray used to treat nocturia, a condition of waking up one or more times to urinate through the night—does not infringe the trademark owned by Plaintiffs Ferring Pharmaceuticals Inc., Ferring B.V. and Ferring International Center S.A. ("collectively, "Ferring") for its own product, "Nocdurna"—an orally disintegrating tablet

that it also used to treat nocturia due to nocturnal polyuria. (*See* Defs.' Answer and Countercl., dated June 28, 2018, Dkt. No. 101.) In response, Ferring asserted an affirmative claim for trademark infringement. (*See* Pls.' Answer and Countercl., dated July 19, 2018, Dkt. No. 115.) Critically, Ferring has only sought injunctive relief to prevent Counterclaimants from future trademark infringement; it does not seek damages for prior infringing acts. (*Id.*)

On November 29, 2018, Defendants moved for summary judgment, seeking a declaration of no trademark infringement and to dismiss Ferring's affirmative trademark infringement counterclaim. (Dkt. No. 321.)

While that motion was pending, Defendant Avadel—the exclusive sub-licensee of Noctiva—filed a voluntary petition for relief under title 11 of the Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware. *See In re Avadel Specialty Pharmaceuticals, LLC*, Case No. 19-10248 (CSS) (D. Del.).[1] In the course of those bankruptcy proceedings (which remain ongoing), several things relevant to the parties' pending trademark claims occurred.

First, the bankruptcy court approved the sale of certain Avadel assets—including Avadel's remaining inventory of Noctiva as well as the regulatory authority from the FDA to commercialize Noctiva—to another entity, Roivant Sciences Gmbh ("Roivant"), "free and clear" of any claims. (*See* 19-10248 Dkt. No. 144; *see also* 19-10248 Dkt. 170 ¶ 9 (Avadel confirmation that sale of assets closed on April 26, 2019).)

Second, over the objections of Serenity (19-10248 Dkt. No. 63), the bankruptcy court ordered the rejection of the manufacturing agreements that covered the production of Noctiva, effective February 6, 2019 (19-10248 Dkt. No. 102).

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[1] References to filings in the bankruptcy proceedings are designated as "19-10248 Dkt. No. __." "Dkt. No. __" refers to the instant docket, 17 Civ. 9922.

Third, a third-party entity—which has never been a party to this lawsuit, but owns certain patents that cover Noctiva—entered an appearance in the Avadel bankruptcy to make clear to any potential purchaser of Avadel's assets that it believed that Serenity and Reprise do not have the right to sublicense any of the company's own technology to any future commercial partner who fills Avadel's shoes and attempts to commercialize Noctiva. (19-10248 Dkt. No. 128.)

Based upon these developments, Ferring now moves to dismiss all trademark infringement claims in this action for want of subject-matter jurisdiction. (Dkt. No. 514.) The gravamen of Ferring's motion is that Avadel's bankruptcy prevents Serenity and Reprise from placing the Noctiva mark "in commerce" in the imminent future, thereby stripping the Court of a justiciable case or controversy.

Ferring's motion to dismiss is *with* prejudice as against Avadel, because the parties have consummated a settlement agreement that, once approved, will resolve all claims between the two parties in this litigation. (19-10248 Dkt. Nos. 203–04 (proposed plan of liquidation and attendant motion to approve).) The motion to dismiss is *without* prejudice, however, as to Serenity and Reprise.

For the reasons that follow, Ferring's motion to dismiss the trademark-related claims for want of subject-matter jurisdiction is granted, thereby rendering moot Counterclaimants' motion for summary judgment.

I. Ferring's Motion to Dismiss

A. Relevant Factual Background

Unless otherwise noted, the following facts are drawn from (*i*) Counterclaimants' Answer and Counterclaims ("Countercl.") (Dkt. No. 101), which is the operative complaint for purposes of Ferring's motion, and (*ii*) filings in Avadel's bankruptcy proceedings.

1. The Parties' Competing Products to Combat Nocturia

Nocturia is a condition of waking up one or more times to urinate in the night. Counterclaimants and Ferring each have developed drugs containing the same active ingredient—desmopressin, which is a synthetic hormone used to treat a variety of disorders related to excessive urine production (Countercl. ¶ 25)—to combat this condition.

Counterclaimants' Noctiva product is a nasal spray containing desmopressin. (*Id.* ¶ 35.) It was the first drug to be approved by the Food and Drug Administration ("FDA") for the treatment of nocturia in the United States. (*Id.* ¶ 36.) Reprise is the lawful owner of all right, title, and interest in two patents that that cover Noctiva—United States Patent Nos. 7,405,203 (the "'203 Patent") and 7,579,321 (the "'321 Patent") (collectively, the "Patents in Suit"). (*Id.* ¶ 7.) Serenity is the exclusive licensee of Reprise's Patents in Suit and owns all right, title, and interest in the Noctiva mark. (*Id.* ¶ 5.) Avadel is the exclusive sublicensee of the Patents in Suit and the "Noctiva" mark. (*Id.* ¶¶ 8–10.) Until it filed for bankruptcy protection and sold its inventory of Noctiva, Avadel was the entity responsible for marketing and selling Noctiva in the United States.

Ferring's Nocdurna product is a "sublingual," *i.e.*, orally disintegrating, tablet of desmopressin. (*Id.* ¶ 37.) Ferring B.V., the parent company of Ferring Pharmaceuticals, Inc., has licensed its rights in the Nocdurna mark to its wholly-owned subsidiary. (*Id.* ¶¶ 15–17.)

2. Attempts to Register the Competing Marks

On August 7, 2009, Ferring filed with the United States Patent and Trademark Office ("USPTO") an application to register Nocdurna for "pharmaceutical products and preparations for use in treating urological disorders." (*Id.* ¶ 46.) This application, which was filed on an "intent to use" basis, was approved on September 24, 2013. (*Id.* ¶¶ 46–47.)

On April 9, 2014, Counterclaimants filed with the USPTO their own application to register the Noctiva mark on an "intent to use" basis. (*Id.* ¶¶ 44–45.) Ferring formally

challenged Counterclaimants' trademark application by filing an opposition before the Trademark Trial and Appeal Board ("TTAB") on November 14, 2015. (*Id.* ¶ 50.) Opposition proceedings, which have been suspended repeatedly for reasons not directly relevant to the present motion, remain ongoing. (*Id.* ¶ 52.)

3. Use in Commerce

Noctiva and Nocdurna are both available for sale in the United States as prescription-only products. (*Id.* ¶ 49.)

On March 3, 2017, the FDA approved Serenity's New Drug Application ("NDA") to engage in the commercial manufacture, use, and sale of Noctiva for the treatment of Nocturia. (*Id.* ¶¶ 35–36.) Noctiva launched for sale in April 2018. (*Id.* ¶ 45.)

On June 21, 2018, the FDA approved Ferring's NDA for the commercial manufacture, use, and sale of desmopressin acetate sublingual tablets, under the name Nocdurna, to the general public. (*Id.* ¶¶ 37–39.) Ferring launched Nocdurna in the United States on November 9, 2018. (*See id.* ¶ 43 (stating that Ferring intends to launch Noctiva in November 2018); *accord* Decl. of Jennifer Accumanno in Opp. Defs.' Mot. Summ. J. ("Accumanno Decl."), dated Dec. 13. 2019, ¶ 5, Dkt. No. 351 (confirming Noctiva launch date as November 9, 2018).)

B. Procedural Background

As the parties well know, this case has a tortured history. The Court, therefore, only will summarize those background facts that are relevant to the instant motion.

1. Present Proceedings

On April 28, 2017, Ferring filed the present action against Serenity, Reprise, and Allergan, Inc.—the entity who formerly stood in Avadel's shoes[2]—in the District of Delaware,

[2] Ferring subsequently dismissed all claims against Allergan. (*See* Dkt. No. 35.)

seeking a declaration that the '203 and '321 Patents are invalid and unenforceable on various grounds. The case was then transferred to this District. It was eventually assigned to Judge Robert W. Sweet, who has since died.

On June 28, 2018, Serenity and Reprise—now joined by Avadel—filed a counterclaim against Ferring seeking declaratory judgment of no trademark infringement. (Dkt. No. 101.)

On July 19, 2018, Ferring filed its own counterclaim against the three entities for trademark infringement, pursuant to 15 U.S.C. § 1114(1). (Dkt. No. 115.) As relief, it sought a permanent injunction enjoining Counterclaimants from all future infringing acts. (*Id.* at 35–36.)

On November 29, 2018, Serenity, Avadel, and Reprise sought summary judgment on their declaratory judgment counterclaim, as well as Ferring's affirmative trademark infringement claim. (Dkt. No. 321.) In support of their motion, they argued that there was no likelihood of confusion between the parties competing "Noctiva" and "Nocdurna" marks, because, among other reasons, (*i*) the two marks are dissimilar, and (*ii*) the purported target market—health care providers and patients—would not likely mis-prescribe or mistakenly consume the wrong product, given the different ways each is administered, the process by which prescriptions are filled, and the different appearance of the products' packaging. (*See* Dkt. Nos. 327, 363 (Counterclaimants' memoranda of law).)

A trial on the parties trademark infringement claims initially was scheduled to begin on January 14, 2019. (Dkt. No. 131 at 6.) For reasons not relevant here, that trial never happened.

2. Avadel's Bankruptcy Proceedings

On February 6, 2019, Avadel filed for Chapter 11 relief in the United States Bankruptcy Court for the District of Delaware. (19-10248 Dkt. No. 1.) Avadel's bankruptcy filings stated that Noctiva—the company's sole commercial product—was suffering from "underachieving sales [and] unanticipated competition," causing the company to incur an "accumulated deficit."

(19-10248 Dkt. No. 10 ¶¶ 7–8.) Avadel's objective in filing for Chapter 11 protection was to effectuate an in-court sale of its assets, including the Noctiva NDA and exclusive sub-license under the Patents in Suit, pursuant to 11 U.S.C. § 363. (19-10248 Dkt. No. 26 at 4–7.)

On the same day, Avadel moved for entry of an order authorizing the rejection of certain "Renaissance Agreements"—so named after the company that manufactured Noctiva—on the basis that potential purchasers would not be interested in acquiring those agreements as part of any future purchase of Avadel's assets. (19-10248 Dkt. No. 11.) In response, Serenity filed an objection, in which it stated:

> [N]either Serenity nor the Debtor [Avadel] manufacture Product [Noctiva] themselves or have an alternative manufacturing source, the Debtor relies (and before the [Exclusive License and Assignment Agreement] was entered into, Serenity relied) on the Renaissance Agreements to source NOCTIVA product manufactured in compliance with FDA's "Good Manufacturing Practices." Loss of access to the NOCTIVA manufacturing capacity at Renaissance would cause a materially adverse interruption in the ability to supply NOCTIVA to fill prescriptions for patients and thereby substantially diminish the value of NOCTIVA. ***Because of the complexity of the nasal delivery device used for NOCTIVA and the requirements for the manufacture of that device to comply with FDA GMP regulations, replacing that capacity and the related know-how could take two or more years***. The continued availability of the Renaissance NOCTIVA manufacturing capacity provided through the Manufacturing Agreement with Renaissance is thus indispensable for the continued commercialization of NOCTIVA. Rejecting the Renaissance Agreements at this time would be fundamentally inconsistent with the Debtor's ongoing obligations under the ELAA Agreement, and would likely ensure that no party would bid for the Debtor's operating assets.

(19-10248 Dkt. No. 63 (emphasis added).)

By order dated March 13, 2019, the bankruptcy court granted Avadel's motion and, effective as of February 6, 2019, deemed the Renaissance agreements rejected. (19-10248 Dkt. No. 102.)

On April 6, 2019, Roivant entered into an Asset Sale and Purchase Agreement with Avadel, pursuant to which Roivant purchased Avadel's existing supply of Noctiva; all marketing materials associated with Noctiva; all "Regulatory Approvals and Regulatory Documentation

related to" Noctiva, including its NDA; and all other books and records related to Noctiva. (19-10248 Dkt. No. 144-1.)

In anticipation of the bankruptcy court's approval of Avadel's asset sale to Roivant, CPEX Pharmaceuticals, Inc. ("CPEX"), a third-party entity that owns certain technology encompassed in Noctiva, filed a "Limited Objection and Reservation of Rights" three days later. (19-10248 Dkt. No. 128.) In its filing, CPEX noted that it had been "monitor[ing] this action" "to ensure that [its] rights were protected." (*Id.* ¶ 10.) It explained that it owned certain "intellectual property, including patents, relating to a nasal spray delivery formulation of desmopressin now marketed and sold under the name Noctiva[,]" which its predecessor-in-interest had licensed to Serenity on March 31, 2010 (hereinafter referred to as the "CPEX License" or "CPEX License Agreement"). (*Id.* ¶ 1.) The CPEX License provided that, subject to certain limited exceptions (not here relevant), neither party could assign its rights and obligations under the agreement without the other party's consent. (*Id.* ¶ 2.)

Pursuant to that arrangement, CPEX consented to Serenity's initial assignment of the CPEX License to Allergan, Serenity and Reprise's initial commercial partner. (*Id.* ¶ 3.) However, when Allergan terminated its relationship with Serenity, it "purported to assign all of its rights under the [CPEX] License Agreement (including rights to CPEX IP)" back to Serenity"—an assignment to which CPEX never consented. (*Id.* ¶ 5.) When Avadel filled the shoes of Allergan as Serenity and Reprise's commercial partner, Serenity purported to grant Avadel a "sublicense to CPEX IP pursuant to the [CPEX] License Agreement." (*Id.* ¶ 6.) CPEX never consented to that sublicense, either. (*Id.* ¶ 7.) In a warning to potential purchasers of Avadel's assets, CPEX stated:

> CPEX has monitored this action and has been in contact with bankruptcy counsel for the Debtor to ensure that CPEX's rights were protected. . . . ***CPEX therefore files this***

> ***Reservation simply to make clear that CPEX disputes the validity of any assignment of rights to CPEX IP by Serenity to the Debtor***—whether in the [Exclusive License and Assignment Agreement, a Noctiva contract between Serenity and the Debtor in which, among other things, rights to CPEX IP are purportedly granted,] any of the other Noctiva Contracts, or otherwise. CPEX does not object to the sale of any of the Debtor's assets. ***CPEX only wants all potential bidders, purchasers, or asignees to be aware of CPEX's dispute concerning the validity of any grants of rights to CPEX IP in the Noctiva Contracts, including but not limited to the ELAA.***

(*Id.* ¶¶ 10–12 (emphases added).)

By order dated April 15, 2019, the bankruptcy court entered an order authorizing Avadel's sale of certain assets free and client of all liens, claims, encumbrances and interests. (19-10248 Dkt. No. 144.)

3. Parties' Exchange of Letters Before this Court

On May 14, 2019—after the case was re-assigned to me—Ferring submitted a letter to apprise the Court of developments in Avadel's bankruptcy proceedings. (Dkt. No. 497.) In addition to notifying me that it had reached a settlement with Avadel (contingent upon the bankruptcy court's approval as part of Avadel's forthcoming liquidation plan) that would resolve the parties' claims against one another (*id.* at 1), it asserted that Avadel's asset sale to Roivant had stripped this Court of subject-matter jurisdiction over the pending trademark-related claims (*id.* at 1–2).

Counterclaimants responded by letter the next day, countering that there was still a justiciable case or controversy because, "Serenity remains the owner of the NOCTIVA trademark and the NOCTIVA product continues to be offered for sale through the distribution channel while Serenity makes arrangements to work with a commercial partner to fill Avadel's shoes." (Dkt. No. 499 at 3.) It continued:

> It is telling that Ferring, despite its assertion that the Court lacks subject matter jurisdiction to address Counterclaimants' summary judgment motion, has not expressed any willingness to dismiss its trademark infringement charge against Serenity and Reprise with prejudice. Instead, Ferring has stated that it seeks dismissal ***without***

> prejudice so that it will be free to reignite the trademark litigation at some later, unspecified date.

(*Id.* at 4 (emphasis in original).)

On May 16, 2019, the Court advised the parties that it would "decide [Counterclaimants'] motion for summary judgment on Ferring's trademark infringement counterclaim unless Ferring dismisses its trademark infringement claim with prejudice by May 25, 2019." (Dkt. No. 500.)

The parties then exchanged an additional round of letters. Ferring emphasized that the Court lacked subject-matter jurisdiction over the parties' trademark claims, and that it could not dismiss its trademark infringement claim with prejudice because doing so "may have preclusive effect" in its ongoing opposition before the TTAB to Counterclaimants' pending application to register the "Noctiva" mark. (Dkt. No. 508 at 1.) Serenity and Reprise accused Ferring of trying to evade an unfavorable decision on the merits of the trademark dispute. (Dkt. No. 509.)

Two days later, Ferring filed the instant motion to dismiss the trademark-related claims. (Dkt. No. 514.)

C. Discussion

Ferring moves pursuant to Fed. R. Civ. P. 12(b)(1) to dismiss both its trademark infringement claim and Counterclaimants' claim seeking a declaration of no trademark infringement. (*See* Pls.' Mem. of Law. in Supp. Mot. Dismiss ("Ferring's Br."), dated May 30, 2019, at 3, Dkt. No. 515.) As noted earlier, Ferring's motion to dismiss is *with* prejudice as to Avadel, but *without* prejudice as to Serenity and Reprise.

Ordinarily, two different rules would govern a litigant's attempts to dismiss its own affirmative claims versus those asserted against it. *Compare* Fed. R. Civ. P. 41 *with* Fed. R. Civ. P. 12. However, where, as here, the basis for dismissal of all claims is that the court lacks subject-matter jurisdiction, a Rule 41 analysis "is irrelevant." *Nike, Inc. v. Already, LLC*, 663

F.3d 89, 94 (2d Cir. 2011), *aff'd*, 568 U.S. 85 (2013). A court can either dismiss the movant's own claims for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1) or "on consent" of the parties. *Id.* at 92–94, 98. Since, as far as this Court can tell, Counterclaimants have not consented to dismissal of Ferring's claim against them—probably for the obvious reason that their motion for summary judgment would independently dispose of all claims over which (they believe) the Court has jurisdiction—the Court's analysis of all claims subject to Ferring's motion to dismiss will proceed under Rule 12(b)(1).

1. Standard Governing Motion to Dismiss for Lack of Subject-Matter Jurisdiction

"It is a fundamental precept that federal courts are courts of limited jurisdiction." *Owen Equipment & Erection Co. v. Kroger*, 437 U.S. 365, 374 (1978). A case must be dismissed for lack of subject matter jurisdiction "'when the district court lacks the statutory or constitutional power to adjudicate it.'" *Nike*, 663 F.3d at 94 (quoting *Makarova v. United States*, 201 F.3d 110, 113 (2d Cir. 2000)).

On a motion to dismiss for lack of subject-matter jurisdiction, the party seeking to invoke the court's subject-matter jurisdiction bears the burden of proving subject-matter jurisdiction by a preponderance of the evidence. *Makarova*, 201 F.3d at 113 (internal citation omitted). As a result, when deciding such a motion, the Court may look to evidence outside the pleadings. *Cortlandt St. Recovery Corp. v. Hellas Telecommunications, S.à.r.l*, 790 F.3d 411, 417 (2d Cir. 2015) (citing *Makarova*, 201 F.3d at 113). Because jurisdiction must be shown affirmatively, that showing is not made merely by drawing inferences from the complaint that are favorable to the non-movants. *Morrison v. Nat'l Austl. Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008).

The familiar standard governing Ferring's motion to dismiss otherwise applies. The Court must accept as true all material factual allegations in the complaint, resolve all ambiguities

in favor of the non-movants, and draw all inference in their favor. *Id.*; *see also J.S. ex rel N.S. v. Attica Cent. Sch*, 386 F.3d 107, 119 (2d. Cir. 2004).

2. Counterclaimants' Declaratory Judgement Claim is Dismissed

The basis for the Court's subject-matter jurisdiction over Counterclaimants' claim is the Declaratory Judgment Act (the "Act"). The Act provides in relevant part:

> In a case of actual controversy within its jurisdiction . . . any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

18 U.S.C. § 2201(a).

The Act "does not expand the subject matter jurisdiction of the federal courts." *Nike*, 663 F.3d at 95. Rather, the phrase "case of actual controversy" in the Act is coextensive with the same types of "Cases" and "Controversies" that are justiciable under Article III of the United States Constitution. *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quoting *Aetna Life Insurance Co. v. Haworth*, 300 U.S. 227, 240 (1937)). To ascertain whether a case or controversy exists within the meaning of the Act, courts must look to the "'all the circumstances'" so as to ensure that "'there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *MedImmune*, 549 U.S. at 127 (quoting *Maryland Casualty Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1942)).

Important for our purposes, an actual controversy must exist at all stages of review—not merely at the time the complaint is filed. "A case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III—'when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome.'" *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quoting *Murphy v. Hunt*, 455 U.S. 478 481 (1982)). "No matter

how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute 'is no longer embedded in any actual controversy about the plaintiffs' particular legal rights.'" *Id.* (quoting *Alvarez v. Smith*, 558 U.S. 87, 92 (2009)).

Here, Ferring submits that, because "there are no commercially available Noctiva products for which Ferring could assert claims of trademark infringement," the parties' trademark dispute no longer presents a live case or controversy. (Ferring's Br. at 2.) It explains:

> There are three categories of Noctiva that are or could potentially be sold in the future:
>
> > (1) Noctiva that has already been sold by Avadel to wholesalers and is, or has been, distributed to pharmacies and physicians;
> >
> > (2) the remaining Noctiva inventory that currently exists, which was sold to Roivant; and
> >
> > (3) new units of Noctiva that might be manufactured at some undetermined point in the future.

(Pls.' Rep. Mem. in Further Supp. Mot. Dismiss ("Ferring's Rep."), dated Jun. 18, 2019, at 1, Dkt. No. 524 (spacing added for clarity).)

The first category (prior sales of Noctiva) does not pose a live case or controversy, Ferring argues, because (*i*) no party to this case currently possesses any units of Noctiva and (*ii*) rather than seeking damages for *prior* infringing conduct, Ferring represents—both in its filings and by the very injunctive relief it seeks for its affirmative claim—that it only wishes to prevent future trademark infringement. (Ferring's Br. at 1–2, 5; Ferring's Rep. at 1, 6; *see* also Pls.' Answer and Countercl. at 35–36.) As a result, "there is no effective relief that this Court could grant" pertaining to Noctiva units already placed in the stream of commerce. (Ferring's Rep. at 1.)

As to the second category (inventory purchased by Roivant), Ferring argues that the Court cannot fashion any relief pertaining to units purchased by Roivant, because Roivant purchased Avadel's inventory of Noctiva free and clear of all claims. (Ferring's Br. at 4–5.)

And as to the third category (future manufacture), Ferring proposes that there are a number of reasons why the prospect of future units of Noctiva's hitting the market does not pose a live case or controversy. (*See id.* at 5–7.)

First, the ***manufacture*** of future units of Noctiva is not imminent. As noted above, *supra* at 7–8, in the course of Avadel's bankruptcy proceedings and over Serenity's objections, the bankruptcy court ordered the rejection of the Renaissance Agreements. Taking Serenity at its word, the rejection of those "indispensable" agreements "caused a materially adverse interruption in the ability to supply Noctiva to fill prescriptions and . . . replacing that capacity and the related know-how could take two or more years." (19-10248 Dkt. No. 63 at 2–3.) Accordingly, no one currently is manufacturing Noctiva, and no one will be able to do so for the foreseeable future. (Ferring's Br. at 6.)

Second, the ***commercialization*** of future units of Noctiva is not imminent by virtue of various developments caused by Avadel's bankruptcy. Serenity and Reprise no longer have a commercial partner who owns the regulatory authority to sell Noctiva in the United States; Avadel sold that authority to Roivant. (19-10248 Dkt. Nos. 144 & 144-1.) Roivant, in turn, does not have a license to the patents that cover Noctiva—those were not part of Avadel's asset sale agreement—which means it cannot sell Noctiva even if another company were able to manufacture it. (*Id.*; *accord* 19-10248 Dkt. No. 132 ¶ 15 (emphasizing that Roivant "is obtaining bare ownership rights," not the intellectual property subject to a license agreement between

Serenity and Avadel).) And there is no indication that Roivant plans to team up with Serenity and Reprise to commercialize Noctiva.

The prospects of finding any new commercial partner to fill Avadel's shoes are, at best, uncertain. Avadel began looking for a commercial partner, or "co-promoter," to assist in the commercialization of Noctiva as early as November 2018. (19-10248 Dkt. Nos. 10 at 23–25 (sworn declaration of Avadel's president).) As part of those efforts, Avadel "contacted twenty pharmaceutical companies and strategic buyers in order to assess their interest level in a strategic transaction with [Avadel]. However, none of these parties made any proposals to enter into a co-promotion agreement with [Avadel]." (*Id.* ¶ 23.) When Avadel put its rights in Noctiva up for auction, only two parties expressed interest (one of which was Roivant), and neither of them wanted to take on terms related to the licensing of patents from Serenity or Reprise. (19-10248 Dkt. No. 132 ¶¶ 8–11, 15 ("[Avadel] ran an open and public sale process in which bidders had the opportunity to purchase the License Agreement [between Avadel and Serenity concerning the intellectual property covering Noctiva] ***and nobody bid on the License Agreement***.").) In fact, part of the reason that Serenity objected to Avadel's asset sale was because not selling the associated intellectual property licenses along with the regulatory authority to sell Noctiva would make it that much harder to commercialize Noctiva in the future. (19-10248 Dkt. No. 140 (transcript of oral argument as to whether the intellectual property and regulatory authority concerning Noctiva were "interrelated").) And the presence of CPEX, who has made it clear that it "wants all potential bidders, purchasers, or assignees to be aware of CPEX's dispute concerning the validity of any grants of rights to CPEX IP" (*id.* ¶ 13), makes it even more difficult for any potential commercial partner to commercialize Noctiva anytime soon.

Third, Ferring asserts that even if Serenity and Reprise were able to find a new commercial partner to fill Avadel's shoes and overcome the manufacturing and commercialization obstacles identified above, "there is no guarantee that the sales and marketing efforts of that new commercial partner related to Noctiva would be identical to or similar to those of Avadel." (Ferring's Br. at 8.) This is especially so if that new commercial partner is not Roivant, who purchased all of the Noctiva marketing materials from Avadel. (Ferring's Rep. at 8.) Because no one can know what evidence of consumer confusion will exist at some uncertain date in the future, Ferring concludes, "[T]o the extent that circumstances change—*e.g.*, Counterclaimants' new commercial partner is forced to adopt new marketing and education strategies—evidence regarding the likelihood of confusion [concerning the two marks] will need to be reevaluated." (*Id.* at 8–9.)

Ferring's motion is compelling. Serenity and Reprise's opposition—which primarily consists of non-responsive arguments—is not.[3]

For example, Serenity and Reprise levy the same charge they raised in their pre-motion letters to the Court and assert that Ferring's motion is motivated by the belief that Counterclaimants will prevail on their summary judgment motion, and so Ferring is seeking to avoid that result. (Defs.' Mem. of Law in Opp. Mot. Dismiss ("Defs.' Opp."), dated June 13, 2019, at 1–2, 11, Dkt. No. 518.)

Even if this were true, it is entirely beside the point. The Court is powerless to consider a claim over which it lacks subject-matter jurisdiction. *See, e.g.*, *Rhode Island v. Mass.*, 37 U.S. 657, 714 (1838). Arguments about the parties' purported motives are irrelevant.

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[3] Even though Serenity, Reprise, and Avadel all moved for summary judgment on their counterclaim, only Serenity and Reprise oppose Ferring's motion, in recognition of the tentative settlement agreement reached between Ferring and Avadel, as well as the fact that Avadel is litigating in the bankruptcy court.

Next, Counterclaimants argue that Ferring's pre-litigation conduct—its sending a cease-and-desist letter, filing opposition proceedings before the USPTO, and then ultimately filing a cause of action for trademark infringement—illustrate that the parties share a "real and substantial" adversity of legal interests. (Defs.' Opp. at 4, 7–8.) These arguments would be persuasive if Ferring were contending that the Court *never* had subject-matter jurisdiction over Counterclaimants' cause of action. But it is not. The theme of Ferring's submission is that Avadel's bankruptcy and its attendant developments have *eliminated* the subject-matter jurisdiction *that once existed—i.e.*, a case that once posed "definite and concrete" issues now presents the Court with nothing to do but issue "an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune*, 549 U.S. at 127 (internal quotation marks and citation omitted). Counterclaimants' emphasis on the prior state of affairs is, therefore, unavailing.

Counterclaimants then turn to the fact that Noctiva is still available in the stream of commerce. They contend, correctly, "that prescriptions for Noctiva can be filled to this day," and that "Noctiva products continue to be offered for sale and distributed." (Defs.' Opp. at 5–6.) It follows, under *Starter Corp. v. Converse, Inc.*, 84 F.3d 592 (2d Cir. 1996) (per curiam), *abrogated on other grounds by MedImmune*, 549 U.S. at 132 n.11, that Noctiva's continued use in commerce is sufficient "'to sustain federal question jurisdiction under the Lanham Act.'" (Defs.' Opp. at 6 (quoting *Starter*, 85 F.3d at 595).)

This argument also misses the mark.

For one thing, it strikes only at the periphery of Ferring's motion, but ignores its core contention. Ferring only seeks prospective relief for Counterclaimants' alleged trademark infringement, and that relief will not be addressed to units of the drug that are currently in the

market. Serenity and Reprise—as mere licensors of certain intellectual property—are not selling Noctiva or filling prescriptions of the drug, and Ferring does not seek an order undoing or modifying the licenses that Counterclaimants have already granted. Even if Serenity and Reprise *did* possess certain units of Noctiva (which they do not), they could not place those units in the stream of commerce, because they lack the regulatory authority from the FDA to do so. As a result, there is no possible remedy that the Court could fashion that targets any units of Noctiva that are still available or will become available for purchase. The only prospective relief that could be fashioned against Serenity or Reprise is an order prohibiting them from entering into licenses using the "Noctiva" name.

Additionally, the facts of *Starter* are distinguishable from the case at bar—and Counterclaimants' failure to grapple with the unique facts of this case are telling.

In *Starter*, the question before the Second Circuit was whether Starter Corporation (the well-known athletic apparel company) could maintain a declaratory action claim for no trademark infringement against Converse (the iconic athletic footwear company) arising from Starter's planned manufacture of a new sneaker. 84 F.3d at 594. Converse contended that Starter "ha[d] not yet begun the manufacturer and sale of its footwear, Starter athletic shoes are not yet 'in commerce,' thus Starter's footwear is not yet subject to the Lanham Act, and therefore no statutory basis for federal question jurisdiction exists." *Id.* at 595. The Second Circuit disagreed and held that Starter's prior use of the mark at issue in connection with different goods sufficed to "place[] the mark[] sufficiently 'in commerce' to sustain federal question jurisdiction under the Lanham Act." *Id.*

Starter, however, is a large sportswear manufacture that was merely opening a new sneaker line. *Id.* at 594. There was no indication that producing those sneakers required a

special manufacturing process, familiarity with Starter's product prototype, or regulatory approval—all of which are issues relating to the future manufacture of Noctiva. Indeed, the Second Circuit observed, "Starter's complaint alleges that but for Converse's threat of a trademark infringement suit, Starter would have been immediately prepared, at the time the complaint was filed, to begin manufacture and sale of shoes bearing the Starter Marks." *Id.* at 596.

Needless to say, that is not the case here. By Counterclaimants' own admission, the loss of Avadel caused a "material[] adverse interruption" (19-10248 Dkt. No. 63) and leaves them potentially two years removed from manufacturing new units of Noctiva—regardless of how the other hurdles associated with commercializing the product are resolved. The Court thus agrees with Counterclaimants that *Starter* is illuminating, as it considered the unique circumstances of the parties and how quickly the competing mark could be placed in commerce. The problem is that *Starter* is not a case that breaks in Counterclaimants' favor.

Counterclaimants next argue that Ferring's continued opposition to Counterclaimants' registration of the "Noctiva" mark before the USPTO "confirm[s] the existence of adverse legal interests between the parties, with sufficient immediacy to allege a case of actual controversy under the Declaratory Judgment Act." (Defs.' Opp. at 7.)

As a matter of law, opposition before the USPTO, standing alone, is *not* sufficient to establish the existence of an actual case or controversy. *See, e.g.*, *Sasson v. Hachette Filipacchi Presse*, No. 15-CV-00194 (VM)(SN), 2016 WL 1599492, at *4 (S.D.N.Y. Apr. 20, 2016) ("Federal courts do lack declaratory judgment jurisdiction where 'the defendants do not object to the plaintiff's current use of the mark' and the only 'immediate and definite controversy is over registration of that mark.'") (citing *Bruce Winston Gem Corp. v. Harry Winston, Inc.*, 09-cv-

7352 (JGK), 2010 WL 3629592, at *5 (S.D.N.Y. Sept. 16, 2010), *1-800-Flowers.com, Inc. v. Edible Arrangements, LLC*, 905 F. Supp. 2d 451, 456 (E.D.N.Y. 2012), & *Progressive Apparel Grp., Inc. v. Anheuser-Busch, Inc.*, 95-cv-2794 (DLC), 1996 WL 50227, at *4 (S.D.N.Y. Feb. 8, 1996)). Without the simultaneous threat of the imminent commercialization of Noctiva, the opposition before the USPTO cannot alone confer subject-matter jurisdiction over Counterclaimants' claim.

Finally, turning to the developments caused by Avadel's bankruptcy—*i.e.*, the heart of Ferring's motion—Counterclaimants write, "Ferring has apparently scoured the Avadel bankruptcy proceedings to identify any and all ongoing disputes among Avadel, Serenity, and Reprise as well as any third parties (which necessarily are referenced during bankruptcy proceeding [*sic*]) to spin a fictional, speculative narrative that 'there are a number of additional roadblocks that may prevent the future commercialization of Noctiva.'" (Defs.' Opp. at 9 (citing Ferring's Br. at 2–3).)

Counterclaimants' use of the word "fictional" is curious. Everything that Ferring reports is reflected on the bankruptcy court's docket. More to the point, Counterclaimants do not otherwise dispute the accuracy of the issues raised by Ferring—some of which came from Serenity's own pages—so the Court is not sure how Counterclaimants settled on that particular characterization of Ferring's "narrative."

Indeed, the only *substantive* response provided by Counterclaimants to Ferring's core contention about the effect of Avadel's bankruptcy is this:

> Serenity is negotiating a commercial arrangement with Proviant. . . . The same is true with respect to other third-party licensees. In any event, Serenity and Reprise . . . expect to close a deal in the near future and expect to continue with sales of Noctiva once that happens. This is more than sufficient for subject matter jurisdiction.

(Defs.' Opp. at 10.)

The only authority cited by Counterclaimants in support of this sweeping assertion is *AARP v. 200 Kelsey Assocs., LLC*, No. 06 Civ. 81 (SCR), 2009 WL 47499, at *9 (S.D.N.Y. Jan. 8, 2009). As with *Starter*, this case is readily distinguishable on the facts and underscores the extent to which Counterclaimants have ignored the substantive factual issues raised by Ferring.

In *AARP*, plaintiff AARP, the non-profit organization dedicated to addressing the interests of persons age fifty and older, published a magazine titled "Modern Maturity," for which it obtained federal trademark registration. *Id.* at *1. While AARP ultimately re-named its magazine, it still offered for purchase back issues of Modern Maturity on its website and used the mark in connection with other products and services. *Id.* The defendants sought to launch a new magazine—also called "Modern Maturity," and also intended for senior citizens. *Id.*

AARP subsequently sued for trademark infringement, and the defendants moved to dismiss for want of subject matter jurisdiction on the basis that they had not yet published their competing magazine. *Id.* at *2. In opposing dismissal, AARP argued that there was a live case or controversy because "defendants ha[d] taken significant steps toward realizing their intent, including by actively seeking licensees to publish [their magazine] and conducting and extensive analysis of the publishing industry." *Id.* at *9 (alterations in original omitted).

The district court agreed and denied the defendants' motion to dismiss for want of subject-matter jurisdiction. In so concluding, it reasoned:

> While defendants may not have settled on a licensing partner, the Court must accept as true plaintiff's allegation that they have been actively searching for one. Plaintiff need not wait for defendants to actually secure that partner before filing suit. Securing a licensing partner to undertake actual publication of the magazine presumably occurs only after one has made a number of concrete decisions concerning the proposed content, design, and layout of the magazine. **Thus, once a licensing partner is identified, little will remain for defendants to do other than commence production, distribution, and sale of the magazine.**

Id. at *9 (emphasis added).

But as Ferring's motion illustrates, producing a magazine (or a sneaker) is quite different than manufacturing Noctiva. Even accepting as true Counterclaimants' assertion that they expect to close a deal with a new commercial partner, Serenity's own representations to the bankruptcy court establish that "replacing th[e] capacity and related know-how" associated with the "complexity of the nasal delivery used for Noctiva and the requirements for the manufacture of that device to comply with FDA GMP guidelines" "could take two or more years." (19-10248 Dkt. No. 63.) Put otherwise, even if Serenity and Reprise were to find a commercial partner tomorrow, that would not resolve the substantial *manufacturing* hurdles they face. Nor would it even necessarily solve their *commercial* issues, because, if Counterclaimants' new commercial partner is someone other than Roivant, then they still will need to create all new marketing and sales materials, since Roivant purchased those assets from Avadel. Accordingly, Counterclaimants' bare assertion that they expect to locate a new commercial partner at some (unspecified) future date, without more, falls well short of establishing that the Court possesses subject-matter jurisdiction over their claim. And it certainly sets this case apart from *AARP*—a case that is not binding on this Court—in which the hurdles to placing the allegedly infringing mark in commerce were fewer and far more manageable.

In summary, the Court finds all of Counterclaimants' reasons for denying Ferring's motion unpersuasive and concludes that this case no longer presents a live case or controversy. Even though the parties "continue to dispute the lawfulness" of the conduct that gave rise to this action, *Already LLC*, 568 U.S. at 91, Avadel's bankruptcy and its concomitant effects on the commercialization of Noctiva have eliminated the Court's subject-matter jurisdiction over Counterclaimants' claim for declaratory judgment, because Counterclaimants lack a "definite

intent and apparent ability to imminently" use the Noctiva mark in commerce anytime soon. *Starter*, 84 F.3d at 596.

As is readily apparent from the foregoing, Serenity and Reprise do not have any Noctiva in their possession to place into the market. They cannot themselves manufacture Noctiva, nor can they readily find a manufacturer to produce Noctiva—a process that could take more than two years to complete. They no longer have a commercial partner to sell Noctiva. A third party exclusively owns the regulatory authority to sell Noctiva in the United States, yet that same third party specifically chose not to purchase the license associated with the intellectual property covering Noctiva. A different third party has implicitly threatened to sue any potential commercial partner who tries to sell Noctiva without receiving that entity's own independent approval. It is anyone's guess how long resolving any of this may take.

In considering Ferring's motion, the court is mindful that "the threat of future litigation remains relevant in determining whether an actual controversy exists." *Nike*, 663 F.3d at 96. "[S]imply holding litigation in abeyance, where a party could forestall litigation indefinitely . . . does not eliminate the case or controversy." *Id.* These concerns are top of mind in a case like this—one that is sprawling, costly, and part of larger, overarching dispute between the parties, spanning multiple courts in various jurisdictions.

But by the same token, the fact that this case has so many moving pieces further counsels against a finding that the Court has subject-matter jurisdiction. Frankly, even after drawing all inferences in Counterclaimants favor—and, as a matter of law, they are not entitled to the benefit of inferences to make a case for subject-matter jurisdiction—it strikes the Court as highly implausible that Counterclaimants will be able to produce and use Noctiva in commerce any time soon. Counterclaimants' silence on this point rings loud and clear.

For this reason, the Court concludes that it does not have subject-matter jurisdiction over Ferring's counterclaim.

The motion is granted.

3. Ferring's Trademark Infringement Claim is Dismissed

Having concluded that the parties' trademark dispute no longer presents a judiciable case or controversy within the meaning of Article III, *MedImmune*, 549 U.S. at 127, the Court no longer has subject-matter jurisdiction over Ferring's affirmative claim of infringement, either. Accordingly, Ferring's trademark infringement claim is dismissed.

II. Counterclaimants' Motion for Summary Judgment

Dismissal of the parties' trademark-related claims moots Counterclaimants' motion for summary judgment. That motion is denied.

CONCLUSION

Based upon the foregoing, Ferring's motion to dismiss the trademark-related claims for lack of subject matter jurisdiction is granted. Counterclaimants' motion for summary judgment is denied as moot.

The Clerk of Court is respectfully directed to close the open motions at Dkt. Nos. 321 and 514.

It is so ordered.

Dated: July 31, 2019

Chief Judge

BY ECF TO ALL COUNSEL